UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,966	10/31/2001	Richard A. Shimkets	15966-551CON S-2 (CURA-51	7979

7590 10/30/2003

MINTZ, LEVIN, COHN, FERRIS,
GLOVSKY AND POPEO, P.C.
One Financial Center
Boston, MA 02111

EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1646	11

DATE MAILED: 10/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,966	SHIMKETS ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Claims 1, 3-8 and 12-14 have been amended and claims 9 and 16-17 have been cancelled as requested in the amendment of Paper No. 9, filed on August 08, 2003. Claims 1-8 and 10-15 are pending in the instant application.

Claims 1-8 and 10-15 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on August 08, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

5. Claims 1-8 and 10-15 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record as applied to claims 1-13 in section 9 of Paper No.8. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

Applicant traverses the rejection on the premises that "a specific, substantial and credible utility [of SEC1/FGF is asserted to be] for detection of inflammatory diseases including psoriasis, Crohn's Disease [...], and for identification of cell proliferative disorders including cancer, and that the nucleic acid or the protein of clone FGF10AC004449 may be a target for therapeutic agents in such disorders" (page 6, last paragraph of the Response). Applicant further argues that because the instant SEC1/FGF of SEQ ID NO: 2 encoded by the claimed nucleic acids has structural homology to the FGF family of proteins and because "members of the FGF family share a specific substantial, and credible utility, as a marker for chronic and acute inflammatory diseases, cancers, and arthritis" (bottom at page 7), one would expect that "a novel member of their protein class, such as SEQ ID NO: 2" (top at page 8), would also have similar functions and, consequently, a specific, substantial and credible utility. These arguments have been fully considered but are not deemed to be persuasive for reasons that follow.

As it was fully explained in the previous office communication of Paper No. 8, section 9, the assertion that the disclosed SEC1/FGF has biological activities similar to known human FGFs is not substantial in the absence of supporting evidence, because the relevant literature reports numerous examples of polypeptides of different well-established families of growth factors wherein individual members have distinct, and even opposite, biological activities. In view of the absence of any information regarding the specific biological significance of this particular SEC1/FGF one would not know which one, or combination of several, of the numerous activities of the FGF class of polypeptides would be attributed to the instant asserted novel FGF family member. The instant specification fails to provide any evidence or sound scientific reasoning that would support a conclusion that the instant SEC1/FGF is associated with

any specific function of FGF family of proteins. Moreover, the art acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases. Based of the information that "Applicants' proteins of the invention possessed over 50% identity to the ADAMTS family of proteins" (page 9, second paragraph of the Response), one skilled in the art would at most conclude that the instant sequences could belong to the same family of proteins or could be to some extent evolutionary related. There are no known teachings in the art that would allow one to make a definite prediction of a protein function based solely on its structural similarities (50%) to a different protein with a known function. If Applicant is aware of any art, which supports such predictions, then Applicant is strongly encouraged to make such art of record.

Therefore, at the time of filing the assertion that "SEC1 nucleic acids and polypeptides may be useful in treating of cancer and other disorders related to angiogenesis including abnormal wound healing, inflammation, rheumatoid arthritis, psoriasis, endometrial bleeding disorders, diabetic retinopathy, some forms of macular degeneration, haemangiomas, and arterial-venous malfunctions" (page 10, lines 25-28 of the instant specification) is found to be unsupported by any evidence of record.

The Declaration of Meera Patturajan under 37 CFR 1.132 filed August 08, 2003 is insufficient to overcome the rejection of claims 1-8 and 10-15 for the following reasons. The Declaration presented new data regarding SEC1/FGF proliferative activity toward BaF3 cells expressing the FGF receptor b2. It was never doubted or disputed that the instant SEC1/FGF might be a novel member of FGF family of proteins and, therefore, would react with FGF receptors. However, the instant specification, as filed fails to present any support regarding

specificity of the instant SEC1/FGF and activation of the FGF receptor b2. At the time of the invention, the information about receptor specificity of SEC1/FGF was not available. Similarly, based on the information in the instant disclosure, a skilled artisan would not be able to use the instant SEC1/FGF sequences for diagnosis of Psoriasis (section 6 of the Declaration). Finally, one readily understands that the use of SEC1/FGF sequences "as a marker to detect the presence of inflammatory disorders" (section 7 of the Declaration) cannot be considered as a specific utility because "inflammatory disorders" represent a broad class of pathological conditions of different etiology, and there is no reasonable evidence available to permit a conclusion that the instant SEC1/FGF is associated with all of them.

Therefore, because the instant specification does not disclose a specific, substantial and credible use for the instant nucleic acids or the encoded protein, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

6. Claims 1-8 and 10-15 are rejected under 35 U.S.C. 112, first paragraph for reasons of record as applied to claims 1-13 in section 10 of Paper No. 8. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

7. Claims 1-8 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 01/18228 document published on March 15, 2001 for reasons of record as applied to claims 1-6 in section 16 of Paper No. 8.

Applicant submits that because the instant specification satisfies the 35 U.S.C. § 112, first paragraph requirement, then the priority date should be awarded as May 14, 1999 (bottom at page 11 of the Response). This has not been found to be persuasive for the reasons of record fully explained in sections 5 and 6 of the instant office action. Thus, the effective filing date of the instant application remains its filing date, which is 10/31/2001.

New grounds of objection or rejection necessitated by amendment

Claim Objections

8. Claims 12 and 15 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 12 and 15 recite "a prokaryotic or eukaryotic cell". According to knowledge in the art, all cells are represented by two types, which are prokaryotic or eukaryotic cells. Therefore, claims 12 and 15 are directed to the same subject matter as claims 11 and 14, respectively, from which they depend.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 14-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 14 is directed to a process for producing a polypeptide. However, the claim depends from claim 1, which encompasses a compliment of a nucleic acid that encodes a polypeptide of SEQ ID NO: 2. The prior art clearly does not teach how to produce a polypeptide by using a nucleic acid that is complementary to a nucleic acid encoding that polypeptide. The instant specification fails to provide any guidance or any working examples on how to practice the claimed invention. It would require substantial amount of undue experimentation on part of a skilled artisan in order to discover how to practice Applicant's invention as currently claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 14 is vague and indefinite for recitation "a polypeptide". Because claim 14 depends from claim 1, and most of the nucleic acids claimed in claim 1 do not encode any polypeptide, it is not clear what "polypeptide" is intended by the claim. Moreover, the metes and

bounds of the recitation cannot be determined from the claim because it is obvious that "cell of claim 11", which comprises "the vector of claim 10", also comprises a plurality of other coding sequences, not necessarily limited or related to SEQ ID NO: 1.

12. Claim 15 is indefinite for being dependent from indefinite claim.

Conclusion

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. *oc*

JOHN ULM
PRIMARY EXAMINER
GROUP 1800